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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/665,036	09/19/2000	Nebojsa Ilic	13297/00002	5475

7590 04/20/2004

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EXAMINER

PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/665,036

Applicant(s)

ILIC ET AL.

Examiner

Patricia A Patten

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-10, 19-23, 34, 35 and 37-39 is/are pending in the application.
- 4a) Of the above claim(s) 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-10, 19-23, 34 and 37-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/4/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 5-10, 19-23 and 34-39 are pending in the application.

Election/Restrictions

Applicant's election without traverse of the species of 'apple' in the response filed 7/1/03 is acknowledged.

Claim 35, solely directed to the non-elected species, has been withdrawn from further consideration as being directed toward a non-elected invention.

Claims 5-10, 19-23, 34 and 36-39 were examined on the merits.

Arguments directed solely to previous rejections which have been removed are moot in light of the new rejections which follow.

Claim Rejections - 35 USC § 112

Claims 5- 10, 19-23, 34 and 37-39 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the previous Office Action because the specification, while being enabling for a method for extracting the crude epicuticular

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layer of plants or plant parts via exposure to a solvent (and the corresponding crude product obtained therefrom) which has some activity against HSV-1, does not reasonably provide enablement for the broad recitation of ' an antiviral substance' purified from any plant.

Applicants contend that they have "....discovered that antiviral preparations may be prepared from the cuticular and epicuticular layers of specific plants and plant parts" (p. 7 first paragraph -Arguments). Although there is some indication in the Instant specification that apple, avocado, cabbage, grape and tomato produced *some* inhibition towards HSV- 1 . Applicant did not disclose what parts of the plants actually produced this 'anti-viral substance' . According to the data presented on p. 16 of the Instant specification, there were two samples of apple- 61 and 64 which showed markedly different inhibitory activities toward HSV- 1 . Thus, the methods set forth in the Instant specification are evidence that the extracts of apple plant (61 and 64) were indeed different with regard to anti-HSV activity thereby providing indication that even similar extractions on the same plant outer-peel produce different effects to anti-HSV activity in-vitro. Therefore, it is *a priori* unpredictable to extrapolate these results to other viruses such as tobacco mosaic, HIV or the flu virus for example. Even the most skilled of artisans would need to perform expensive, time consuming trial and error protocols in order to determine if the claims are functional within their broad scope, constituting ***undue experimentation***.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-7, 9, 10, 19-23 and 38-39 are rejected under 35 U.S.C. 102(b) as being anticipated Sal'kova et al. (1981).

Sal'kova et al. (1981) taught a method for extracting antioxidants from apple coatings via placing ('dipping') whole apples (it is noted that the only part of the apple 'dipped' is the 'peel' of the apple i.e., claim 39) into a beaker of hexane, distillation of the solvent (solvent removal) with heat to produce a waxy precipitate which was further filtered and analyzed (Experimental, p.219). The Antioxidant profile can be seen in Figures 1-3, and the purification scheme is found on p.220. It is deemed that because Sal'kova did not teach heating the solvent until the clarification process, that the hexane was at room temperature (claim 38).

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It is deemed that dipping/placing the apples into the beaker of hexane for one minute would have released the waxy layer (cuticular/epicuticular waxy layer) but would not have dissolved the skin of the apple, especially lacking convincing evidence to the contrary. It is also noted that the final extracted product was dissolved in acetone, which is considered a biologically compatible medium. Because the product was distilled to remove the solvent, it is deemed that the product was clarified (as in claim 21).

The language in claim 22 which states 'further comprising formulating the antiviral preparation into a pharmaceutical composition' is very broad. It is deemed that again, because the product was distilled to remove the solvent, that the end product does not preclude its use as a 'pharmaceutical composition'. It is noted that this language in the claim does not specifically recite particular method steps, and therefore it is deemed that any steps in the prior art method which produce a product which would not be pharmaceutically detrimental *per se*, anticipates the claimed invention.

Claims 5, 9-10, 19-23, 34, 37 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Archer et al. (1971).

Archer et al. (1971) disclosed a method for analyzing Kethane deposits on Gravestine apples (Abstract). Their study included peeled and cored apples, as well as apples sprayed with Kelthane and apples not sprayed with Kelthane as the negative

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control (please see Table 1, p.1328). Archer et al. specifically taught, "Approximately 1,400 g of sprayed apples were washed with either redistilled ethyl alcohol or redistilled benzene solvent. The apples were washed seven times with two liters of solvent at 65 to 75° C for **5 min.** with agitation (p.1327). It was reported that the benzene wash removed 92% of the original Kelthane residues (p.1328 and Table 4).

Therefore, Archer et al. anticipated the claimed invention.

It is again noted, that the language in the claims which recites 'possessing antiviral activity' and 'antiviral preparation' is not given much weight. With regard to composition claim 10 which states 'antiviral preparation', it is noted that "[E]ven though product-by-process claims are limited by and defined by the process, determination **of patentability is based on the product itself. The patentability of a product does not depend on its method of production.** If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted, emphasis added) MPEP§ 2113. In the Instant case, it has been determined that the process performed by Archer et al. would have created the broadly claimed composition since the method outlined by Archer et al. would have yielded an extract containing solubilized materials in the cuticular and epicuticular layers of the apple. No discernable

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difference can be made with regard to the product disclosed by Archer et al. and the product as Instantly claimed.

With regard to the method claims, the language 'for producing a preparation possessing antiviral activity' is merely relaying an inherent property of a known composition and does not hold much patentable weight: In view of In re Sussman, 141 F. 2d 267, 60 U.S.P.Q. 538 (CCPA 1944), " since the steps are the same, the **results must inherently be the same unless they are due to conditions not recited in the claims.**" (emphasis added). In the particular case, Applicants are claiming an invention employing the same process steps but are alleging the product and the methods of the Instant claims to be different from the prior art.

It is clear that the prior art taught removal of the outer layers of apple skins in order to evaluate these layers for contaminants and or antioxidant activity. Although the prior art did not teach the specific properties of anti-viral activity, the products were none-the-less known, as too were the methods for producing the products. Applicants have not provided any *particular clarification process* which would exceed beyond what is already known in the art: removal of the outer layers of waxy residue present on apple skins. For example, Applicants have not disclosed a particular compound which is purified from the crude waxy organic solvent 'dip' extract which would indicate that Applicants work exceeded what was already known in the prior art. Although the anti-

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viral activity of the outer layer of apples appears to be new, Applicant is asked to review *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). "When the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated" (MPEP 2100 pp. 2113) as in, for example, claim 10.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-10, 19-23, 34 and 36-39 are rejected under 35 U.S.C. 103(a) as being obvious over Archer et al. (1971) in view of McMurray (1992).

The teachings of Archer et al. (1971) were discussed *supra*.

Archer et al. did not specifically teach dissolving the outer layer of apples with a solvent as listed in claim 6 or wherein the step of exposing the plant with a solvent included spraying the plant.

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McMurray (1992) teaches that hexane and benzene have quite similar polarities (they are both non-polar, organic solvents) (please see Table 11.2, p.385).

The ordinary artisan would have been motivated to use benzene as a substitute for hexane because it would have been clear that benzene and hexane would have been virtual equivalents with regard to non-polar solvent extraction. The ordinary artisan would have had a reasonable expectation that hexane would have substantially dissolved the outer layers of the apple because of the similar polarity hexane has to benzene especially absent convincing evidence to the contrary.

The ordinary artisan would have been motivated to spray the solvent onto the apples in order to extract the waxy layer because spraying the solvent onto the apples would have sufficiently dissolved substances in the cuticular or epicuticular layers of the apple. It was clear from Archer et al. that dissolving the waxy outer-layer of the apple was dependant upon contact with the solvent. The ordinary artisan would have readily recognized that contact with the solvent, either by spraying, or by dipping would have dissolved the outer coating of the apple since the solvents were lipid soluble, non polar solvents.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

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ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A Patten whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0968. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia A Patten
Examiner
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4/12/04

A handwritten signature in cursive script, reading "Patricia A. Patten".

PATRICIA PATTEN
PATENT EXAMINER